K110782

APR - 7 2011

510(k) SUMMARY

SUBMITTER:

Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

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DATE PREPARED: March 18, 2011

DEVICE TRADE NAME: XVAC

COMMON NAME: Vacuum module

CLASSIFICATION NAME: Apparatus, Autotransfusion

PREDICATE DEVICE: Dideco Vacuum Pump (K936220)

DEVICE DESCRIPTION:
The XVAC vacuum module is an enhancement of the predicate Dideco Vacuum Pump. Similar to the predicate device, the main components are the housing, the aspiration pump (with the exception that XVAC includes two different pumps: one for intraoperative mode and one for postoperative mode), and cooling fan.
The main modifications consist in the newly designed system that integrates software, control and monitoring sensors and an user interface (display, LEDs, speaker and touch panel).

INDICATION FOR USE:
The XVAC is intended for use in autotransfusion, for the aspiration of shed blood (which is subsequently processed and reinfused to the patient) in the operating room or patient care areas.

TECHNOLOGICAL CHARACTERISTICS:
Sorin makes the claim of substantial equivalence to cited predicate based on intended use, fundamental technological characteristics, and principles of operation.

Sorin Group Italia Srl believes that the XVAC is substantially equivalent to the Dideco Vacuum Pump. Any differences do not raise any new issues of safety and effectiveness.

IN VITRO TEST RESULTS:
Testing supplied in the 510(k) premarket notification for the XVAC includes electrical testing, electromagnetic compatibility testing, and performance testing that demonstrates compliance with performance specifications.

CONCLUSIONS:
The XVAC is substantially equivalent to the Dideco Vacuum Pump in terms of functionality. Similar to the predicate device the XVAC is an AC powered vacuum pump that provides adjustable vacuums and is indicated for the aspiration of shed blood in the operating rooms or patient care areas.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Italia S.r.l.
c/o Mr. Barry Sall
Principal Consultant
195 West Street
Waltham, MA 02451

APR - 7 2011

Re: K110782
XVAC
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: March 18, 2011
Received: March 21, 2011

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110782

Device Name: XVAC

Indications for Use:
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Prescription Use __X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110782